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DEVITA ACCEPTS "CHOP LIKE" CANCER CONTROL ELEMENTS IN CCOP; RFA DELAYED UNTIL AFTER MAY NCAB MEETING

Resolution of the remaining controversies involved in development of the Community Clinical Oncology Program came into sight last week when NCI Director Vincent DeVita agreed to:

1. Incorporate "CHOP-like" elements of cancer control into the

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In Brief

DAVID JOHNSON NEW ACCC PRESIDENT, WILLIAM DUGAN NAMED PRESIDENT ELECT; STRAUS RESIGNS FROM NYMC

DAVID JOHNSON, administrator of Deaconess Hospital in Evansville, Ind., is the new president of the Assn. of Community Cancer Centers, succeeding Herbert Kerman at last weekend's annual meeting of the association. William Dugan, Indianapolis medical oncologist, was named president elect. Others elected were Edward Moorhead, Grand Rapids, secretary; Robert Clarke, Indianapolis, treasurer; and Stephen Carter, Palo Alto; Gilbert Friedell, Worcester, Mass.; John Travis, Topeka; and Jennifer File Guy, Columbus, Ohio, trustees. . . . ADOLPH FEIBEL, president of the Greater Cincinnati Cancer Control Program, received the ACCC Annual Award for Outstanding Service. . . . CHARLOTTE FRIEND, HAROLD RUSCH will receive the 1981 Pap Awards, Julius Schultz, president of the Papanicolaou Cancer Research Institute has announced. Rusch, founder and director emeritus of McArdle Laboratory for Cancer Research at the Univ. of Wisconsin, received the award for distinguished service. Friend, director of the Center for Experimental Cell Biology at Mount Sinai School of Medicine, won the award for scientific achievement. . . . JOSEPH HIGHLAND has left the Environmental Defense Fund to head the applied research program on environmental problems at Princeton Univ. He has been replaced as toxic chemicals scientist by Ellen Silbergeld, formerly chief of the neurotoxicology section at the National Institute of Neurological Diseases & Stroke. Highland served on NCI and National Toxicology Program advisory groups. . . . DONALD BROWN, pioneer in the use of recombinant DNA techniques, has received the Ernst W. Bertner Memorial Award from M.D. Anderson Hospital. Brown is director of the Dept. of Embryology at the Carnegie Institution. . . . MARC STRAUS, whose grant at New York Medical College has been terminated by NCI, has resigned as chief of neoplastic diseases to go into private practice. The NIH investigation of charges of unethical conduct while Straus was at Boston Univ. will continue. . . . CONSENSUS STATEMENT on computed tomographic scanning of the brain, developed at an NIH conference last November (*The Cancer Letter,* Nov. 27) may be obtained from Michael Bernstein, Office for Medical Applications of Research, NIH, Bldg 1 Rm 216, Bethesda, Md. 20205. Single copies are free.

KATTERHAGEN SELLS DEVITA ON ADDING CONTROL ELEMENTS TO FIRST CCOP RFA

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initial CCOP request for applications.

2. Delay issuance of the RFA until after the May meeting of the National Cancer Advisory Board, giving the Board one final opportunity to help shape the program.

CHOP is the Community Hospital Oncology Program, in which 23 hospitals or consortia are funded through NCI contracts to organize all elements of a cancer program except clinical research. CHOP is still in its early stages, with the participants completing a planning phase and getting ready for implementation.

DeVita had resisted including nontreatment cancer control activities as those that would be supported by NCI in the first CCOP awards, saying that those could be added once the program was functioning with the primary activity it was designed to support, clinical trials.

The Assn. of Community Cancer Centers and its Clinical Research Committee, which helped draw up preliminary guidelines for CCOP, had insisted that some nontreatment control be included from the start. Others argued that since CCOP was being funded through the Div. of Resources, Centers & Community Activities with money earmarked for cancer control, it had to have some cancer control in it.

DeVita's position was that good clinical research in community hospitals is cancer control, that support of clinical trials in communities was a valid use of cancer control money, and that trying to include other control projects initially might complicate implementation and certainly would reduce the total number of CCOPs funded because of the increased cost for each.

The NCAB Cancer Control & Community Subcommittee met last week, charged by the Board to determine if the program as proposed by NCI was ready for an RFA, or if the Board should have further input into it. Subcommittee Chairman Gale Katterhagen, in a statement he presented to subcommittee members, came up with a reason for including at least some control elements from the start which helped change DeVita's mind: participation by the community and community physicians, necessary to secure availability of cancer patients for clinical trials, is much more likely if they are involved in cancer control programmatic activities.

"Gale's suggestion for imposing CHOP like activities onto CCOPs is a good one," DeVita said. "But don't think it will be done without increased cost. Instead of funding from 100 to 200, the total number will drop."

"I would rather have 50 excellent CCOPs than 150 guaranteed to fail," Katterhagen said.

Katterhagen's statement follows:

I have spent some time reviewing the basic concepts and issues which surround the proposed CCOP initiative. As I reflected on the year long development of this program, and reread the documents prepared by NCI staff, the ACCC Clinical Research Committee and the [NCI] Committee on Technology Transfer & the Community, I realize that part of the recent confusion relates to the multiple individuals, communities, and organizations it will affect.

This is a powerful concept. We should anticipate that it may fundamentally alter several existing relationships...and hopefully bring both new resources to the National Cancer Program and new resources from the NCP to the citizens and patients of the country.

What Are We Trying To Accomplish?

This is a critical point. Multiple groups recognize that the CCOP concept can help them meet their own objectives. However, it is important that we be clear about which objectives we are trying to meet for the national effort.

The CCOP initiative began with some conversations between NCI and the leadership of the ACCC. There were two issues initially discussed: How do we increase the numbers of patients on clinical protocols? How do we maximize the impact of the NCP on cancer patient care?

Essentially, Dr. DeVita suggested a quid pro quo: A program that funds development of advanced community cancer programs which, in turn, enter new patients on clinical trials.

It is important to consider why both the community and NCI are interested in the quid pro quo.

NCI, for its part, is concerned with:

- The decline in number of patients put on protocol at university-based cancer programs. The number of patients entered on protocol at universities has declined in recent years as the number of oncologists trained at university cancer centers and moving to the community has increased.
- The difficulties in finding some types of early stage cancer patients for clinical research. Universities see most patients quite late in their disease (stages 3 and 4). This means that protocols for early stage patients are difficult to complete. These patients are plentiful in community hospitals.
- NCI's role in ensuring that technology continues to advance. The effect of the circumstances discussed in the two prior paragraphs is that we are potentially, unintentionally allowing half way technology to continue in our communities. For example, because there is currently an excellent protocol for Hodgkin's, it is being widely used by community oncologists on many patients they see. However, this minimizes the number of patients available for clinical research and, thus, in effect, prevents us from developing new, more effective therapies that will cure a higher percentage of patients.
- NCI's role in ensuring that the most effective management techniques are available and used in community cancer care. This is a congressional mandate, one which was reinforced by the Hawkins hearings last year. One of the basic concepts of cancer control is to assure that communities have access to available technologies, and put proven methods into rapid, widespread application.

The community, for its part, is interested in:

- Developing programs which help bring all cancer patients better organized and integrated cancer management. Many oncologists have tried to replicate the physical facilities, personnel resources, interdisciplinary team organization, and coordinated programs they experienced during their training which can provide high quality care for all patients. But, coordinated programs are a recent innovation in community hospitals. While some have been developed without federal resources, the most advanced programs are those which have gone about it methodically, such as the COPs and more re-

cently the CHOPs. These programs affect a large percentage of patients (@80-90 percent).

• Maintaining an involvement in clinical research. Many community oncologists were trained in an environment where research was an integral part of care. They remain interested in research, but, in community practice have been denied some means of participating in clinical research.

Thus, the CCOP concept as initially discussed, meets the needs and interests of both NCI and community oncologists.

How Can A CCOP Integrate Both Cancer Control And Clinical Research?

The discussions over this past year have focused on how a Community Clinical Oncology Program could be constructed which would provide adequate resources to meet both NCI and community objectives. While the requirements of an effective community-based program are well known, the requirements of a community based clinical research program are different. Thus, most of the discussions have focused on the clinical research component. This is an important point: While most of the recent conversations have emphasized clinical research, it is only part of the program.

Both clinical research and cancer control components are essential to maximize the impact of the CCOP and meet the objectives of NCI and the community.

Why is cancer control important to clinical research in a CCOP?

There are several approaches to getting patients onto clinical trials. One approach is to depend on the medical oncologist to enter patients on protocols. A second is to give primary care physicians direct payments for putting patients on protocol. A third approach is to develop a community program which involves both specialists and primary care physicians.

Medical oncologists can enter some patients on protocol without involvement of other specialists. However, this kind of program only affects those patients seen by medical oncologists and is limited in the number and types of patients that will be available to protocols. Research has shown that 50 percent of cancer patients are first admitted to community hospitals by physicians who see 10 or less cancer patients each year.

Direct payments to primary care physicians (internists, family physicians, and surgeons) to put patients on protocol is an incentive to their participation (although hardly adequate compensation). Yet, this type of program diverts resources from data collection, program organization, and again, limits participation.

Development of a community wide program involves both specialists and nonspecialists in cancer activities. This is best exemplified by the CHOP programs. Development of voluntary patient management guidelines by the physicians who admit 75 percent of cancer patients ensures that a broad spectrum of physicians are aware of modern cancer management techniques and are aware of the benefits of proper pretreatment evaluation, staging, consultations and available protocols. A recent publication by Tucker, et al points out that the COP/CHOP process can affect 80 percent of cancer patients by changing the patterns of care. Although data is not yet conclusive, it appears that this change alone may positively impact mortality, length of survival and quality of care for many patients. This is cancer control at its best!

Locally developed patient management guidelines also serve as a "pathway" to putting appropriate patients on protocol, since they can indicate when a patient may be eligible for an available protocol. An algorithm of a guideline is usually attached to a patient's chart on admission or after histopathologic confirmation. Thus, primary care physicians are alerted to those patients who may be eligible for protocol.

It appears that, for a number of reasons, cancer control is essential to ensuring that the clinical research component of the program will work. In and of itself, the cancer control portion of CCOP may affect 80 percent of patients. The clinical research component may directly affect 10 percent of patients. These are both very impressive potentials.

Why is clinical research important to cancer control?

Clinical research was the one component **not** included in the CHOP programs. The fact that many CHOP principal investigators have expressed interest in CCOP is an indication of how important a component it is. Clinical research is a way for the community oncologist to stay in tough with his/her field.

Dr. DeVita and some others have suggested that involvement in clinical research may impart to community physicians a more rigorous approach to all cancer therapy. In this way clinical research may impact on far more than the 10 percent of patients it will directly impact. As one author has recently suggested, "This is a hypothesis worth testing!"

What Are The Objectives We Are Trying To Achieve Through The CCOP Initiative?

More than just NCI and the community will be required to make the CCOP initiative work. Among the national objectives which CCOP may impact are:

• Objective No. 1 – The need for an evaluation of the impact of clinical research on community cancer care.

• Objective No. 2 – The need to make access to clinical protocols available to more patients and patients with different stages of the disease.

• Objective No. 3 – The need for better organized community cancer programs which can positively affect the patterns of care by involving specialists and non-specialists in collaborative, multidisciplinary cancer patient management.

• Objective No. 4 – The need for a network of community hospitals which can serve as a base for toher NCI programs in cancer control (i.e., large scale chemoprevention trials).

• Objective No. 5 – The need to build the capacity of facilities in geographic regions to work together through either regional cooperative groups or cancer center networks.

• Objective No. 6 – The need to strengthen existing national cooperative groups by appropriately increasing group membership.

When we review these objectives, it is clear the CCOPs will involve patients and their families, a broad spectrum of primary care physicians, community oncology specialists, cancer centers, regional and national cooperative groups, and NCI.

It is no wonder that CCOP appears to parallel the old elephant/blind men story. Everyone is grasping the part of the concept closest to them. To work it will take all the parts in some reasonable, orderly fashion.

What Will It Take To Work?

In outline fashion, here are the components of a CCOP as suggested in the [draft] RFA with additions from the two committees, the DRCCA Board and others:

For the community to participate:

It must be a program which is both control and clinical research, affecting all patients not just those in clinical research. This was the original quid pro quo, and is most likely exemplified by NCI's CHOP programs with their voluntary patient management guidelines, wide scale community physician involvement and programs in rehabilitation, nursing and terminal care.

It must include funding for data management of clinical trials and the patient management guidelines information, including protocol nurses, abstractors and/or data management systems.

It must include funding for an administrator and secretary to hold the program together, supervise data collectors, quality control and to manage the "CHOP type" activities.

Thus, it must provide the community with funding for both the control and clinical research components. If clinical

research is $1000/patient at 50 patients, the control administrative component is likely to be about $400/patient, with significant economies of scale.

It will require the involvement of the community physicians as full partners with their research base affiliates.

It will require flexibility in the choice of research bases. The "appropriate" research base may not always be the closest.

It will require direct funding of communities.

For cancer centers and cooperative groups to participate:

It will require funding for their involvement in quality control, and data collection/analysis. Some centers will not require any funds, but most will. Preliminary estimates are about $300/patient with economies of scale.

It will require the time to develop new relationships with community hospitals and the negotiation of new multiple agreements with CCOPs.

It will require cancer centers to give new emphasis to clinical research efforts and, in conjunction with community physicians, review protocols, change them, and have NCI approve them.

It will require centers to increase their resources in clinical trials management, and biostatistics.

There are also some policy and additional technical issues which must be clarified prior to release of the RFA:

–Will all comprehensive and specialized cancer centers and all cooperative groups automatically qualify as "research bases?" Some do not have very large or sophisticated clinical research programs.

–Can there be two large research base affiliations? For example, can a CCOP affiliate with both a local center (which may have only a few protocols) and a national cooperative group? Would this provide a stepping stone from national to regional groups? How complicated would management of two major affiliations be?

–How will the timing of this solicitation interface with the regional cooperative group funding? [Review of applications from new regional groups is in progress.] Can we ensure that winners of regional groups are notified early enough to be able to participate competitively?

–Should there be planning grants and some type of two-phase effort? Only some communities will be at an advanced enough level to do both clinical research and cancer control. Perhaps we should fund some for an operational phase and some for planning.

–Who will review these submissions? And, what will the review criteria be? If we have only clinical researchers review the submissions, then the focus will be on funding experienced clinical researchers only. As noted above, this will not guarantee success by any means. If we have only those with cancer control experience, then we will see an opposite skew. We need reviewers who will look for overall capability to organize and manage this type of effort in a community setting.

–Who can qualify for an operational CCOP? Should we allow existing full members of cooperative groups to drop their current group affiliations, compete for a CCOP, and then re-enter their group with funding from a different pot of dollars? (This seems unnecessarily costly for NCI, since they have already reviewed and approved most of these applicants.)

–Should "research base" funding for their involvement with CCOP come directly from NCI, or should it be negotiated between each potential CCOP and each research base? What do we do if the centers negotiate different funding schemes with different CCOP applicants? Do we fund the CCOPs that are just better negotiators? Do we put research bases in a position of costing some CCOPs out of the market?

–Do we evaluate the quality and capabilities of the community or of their research base affiliates? What if the research base is a CCOP's nearest center and the center has nothing special to offer?

(Given the above), What Should the CCOP RFA Contain?

It seems the following need to be general provisions:

1. To qualify for an operational CCOP:

- A "CHOP-type" community organization with the equivalent of a CHOP's organization and activities subsequent to the planning phase (i.e., patient management guidelines developed through a large scale participatory process, guidelines on the chart, some organizational structure, some organized programs in nursing management, rehabilitation, and terminal care).
- The documented capability to put at least 50 patients per year on protocols. This minimum will be readily surpassed by many applicants in that I suspect we will see consortia of hospitals apply.
- A preliminary negotiated relationship with a research base which covers protocols to be used, data collection, quality control measures.

2. Operations funding that covers:

- Cancer control/administrative aspects from the outset, including an administrative director, secretary, site committee review and update sessions to keep guidelines current; registry/cancer data systems, evaluation of patterns of care, non-care related administrative duties of a medical director, basic organizational activities in support of organized programs in rehabilitation, and nursing care management guidelines and terminal care.
- Clinical research aspects, including data collection, quality control, funding to cover unreimbursed procedures, drugs, group or center meeting travel.
- Research base costs, including extensions of existing quality control, data analysis activities.

This is about $400/patient + about $1000/patient + about $300/patient = about $1700/patient with economies of scale.

3. What policy stands should we take?

–That both cancer control and clinical research should be included in CCOPs from the outset.

–That cancer control aspects can be represented by CHOP-type activities.

–That those requirements (noted above under requirements for community and for centers and groups) be considered essential to the RFA.

–That the RFA suggest three budgets be submitted: one for control/administrative, one for research and a third for research bases.

–That NCI staff review existing centers and determine which have the capacity to serve as research bases (i.e., minimal technical capabilities, sufficient range of independent protocols, desire).

–That we leave to staff the decision about one versus two major research base affiliations, but recommend that fewer is better.

–That we ask staff to ensure that regional group awards be announced at the earliest possible moment to facilitate their involvement in CCOPs.

–That we recommend that a substantial portion of the FY '83 budget for CCOPs be devoted to planning grants. If the total is $10 million, perhaps four million could go to 40/year planning grants. Then a competition could choose the best of this group and let another round of planning grants (and so on until we reach the number of functional CCOPs desired).

–That we insist there be clinicians, community program experts, and evaluators in the review, and that the review criteria be explicit in the RFA.

–That we prohibit full members of cooperative groups from switching or dropping their cooperative group membership and competing for this solicitation.

—That we insist on a separate budget from research bases that will be evaluated separately. If a CCOP is considered to be excellent, and the budget for a research base is inadequate, NCI can renegotiate or fund research bases separately.

—If research bases are inadequate (or if one is unavailable) a CCOP with good marks can have the opportunity to be funded and negotiate a new major affiliate within a short period of time.

—That we evaluate the entire program including the hypothesis of transfer of technology through clinical research.

Subcommittee member William Powers agreed with Katterhagen on the need for cancer control in the program.

"I'm not sure this will reach where it is needed without control," he said. "CHOP has a significant amount of control. That might be the approach we should take."

Powers said he had other concerns. "Participation in clinical trials is not as easy as you think. The designation of centers (as comprehensive) has given them a certain type of aura, which is not fair to other centers, and the CCOPs would have that too." Powers previously had mentioned fears by some community hospitals and physicians that CCOP hospitals would, by the fact of designation, attract patients away from others. "The CHOPs don't do that, because they are more involved with the community."

Powers also suggested that planning grants should be part of the initial RFA.

DeVita has resisted including planning grants in the first round because "if we get enough good applications without planning grants, we won't need them."

DRCCA Director Peter Greenwald said that the process of developing the program over the past year "has already set up a dialog (between communities and their potential research bases in universities and cooperative groups) that's been scant in the past."

Stephen Carter, chairman of the DRCCA Board of Scientific Counselors, pointed out that his Board has among its members representatives of cancer centers and two large cooperative groups as well as two community physicians. A committee of that Board headed by Charles Moertel worked with the ACCC committee in drawing up the outline of the program.

"The input from outside NCI has been large," Carter said. "I firmly believe that clinical research in the community is superb cancer control. On that basis, the DRCCA Board had not problems with this as a control program."

"It seems to me that the CHOPs (and its predecessor Community Oncology Program) and the Cooperative Group Cancer Control Program have been more than successful," Powers said. "The community components of the cooperative group program that I have observed have been at least as high quality as those in the universities."

Powers agreed that adding CHOP elements to CCOP would enhance the program.

Katterhagen and subcommittee member Rose Kushner objected to lack of details on CCOP being available from NCI. Staff had provided the subcommittee with a four page summary of the program along with the 19-page report of the ACCC committee headed by Edward Moorhead.

"There will not be much in the RFA that you don't already have," DeVita said. "It boils down to making us define things we don't know how to define. We can't spell out every dime."

"We're not asking you to," Katterhagen said. "We all know that in treating cancer, the best chance for cure is your first shot. I think that will hold true with the CCOP RFA. If it goes out unclear, it may fail, and will be impossible to correct with second or third efforts."

"All right, let's sit here and hammer out the details now," DeVita said. "We'll put into this whatever the Board tells us to."

"Unless you have a program that includes patients, their families, the physicians, specialists, you won't have a successful program," Katterhagen said. "The CHOP structure would guarantee more patients. Look at who controls patients, and how referrals are generated. Seventy to 80 percent are not controlled by cancer specialists. Unless you have family physicians feeling they are part of the program, it won't work."

Moorhead and ACCC President Herbert Kerman agreed that ACCC members were disturbed that non-treatment cancer control had been excluded. Kerman pointed out that in the CHOP competition, 23 of 60 applications were funded. "A number of those not funded are still out there with programs."

"A CHOP-like requirement would prevent institutions from applying which don't have community cooperation," Katterhagen said.

Kushner and others have criticized the lack of specific dollar figures in discussions of the program by NCI staff. Some estimates have mentioned a cost of $1,000 per patient for the CCOPs, plus varying amounts for the research bases.

"The only figure I absolutely know," DeVita said, "is $10 million maximum for CCOP in 1983. Not stating precisely the relationships to research bases and the cost of research bases has driven everyone bananas."

Moorhead said the ACCC committee had estimated that 15 percent of the CCOP funding should go into the CHOP like control elements. "Also, any community hospital participating in the program will have to come up with some community support for cancer control projects."

Kushner objected to specifying a minimum of 50 patients each CCOP will be required to enter into clinical trials. "I would hate to be patient number 45

to 50 and be subjected to that kind of pressure. Do you need a definite figure?"

"Yes," DeVita said. "We have to maintain a requirement for participation."

"But tithing sounds like a bounty hunter to a patient," Kushner said.

"You're not going to show the RFA to patients, are you?" DeVita responded.

DeVita insisted that some community physicians have told him they "are sure they can be successful CCOPs without any funding. All they want are access to experimental drugs."

"They would have to be independently wealthy," Katterhagen said.

"No, they said the hospital would foot the bill for data collection," DeVita answered.

"What they want are neon signs on their hospitals that they are CCOPs, and steal patients from other hospitals," Powers said.

"That's a very controversial issue," DeVita admitted.

Carter objected to the prospect that some protocols which will be used in the program, including all of those used by cooperative groups, will be reviewed by NCI while some others developed at centers will not.

"My god, you're not suggesting we review all of them, are you?" DeVita asked. He said review of center core grants plus institutional review board review of protocols should be sufficient. "We don't peer review pilot studies. We try to leave some flexibility."

Carter argued that under that system, a center could initiate a protocol and it could be used by an affiliated CCOP which would be rejected at the start if proposed by a cooperative group. "You would have the situation where specific money supports specific research you haven't peer reviewed in the normal way you review clinical research," Carter said.

"A center would be crazy to let a CCOP use an inappropriate protocol when they know we'll eventually be seeing it," NCI Deputy Director Jane Henney commented.

DeVita wrapped up the discussion by agreeing to include the CHOP like components in the RFA. "I don't think it will be too much different from what we had in mind," He said the delay would not disrupt the proposed review schedule which would permit start up with 1983 fiscal year money.

The subcommittee earlier had resolved the issue of whether to delay the RFA to the NCAB May meeting when all members agreed that the Board should have another look at the program. The final RFA draft itself will not be brought to the Board despite the legal opinion Kushner obtained which said that anyone seeing an RFA or RFP before it is published may still compete in that project provided sufficient time is given after publication to allow anyone else to compete.

NCI policy will remain that prepublication viewing of an RFA or RFP will disqualify participation.

Kushner and Powers, in arguing for the delay, both insisted that they "enthusiastically" support CCOP and only hope by delaying the RFA to strengthen the program.

CCOP issues dominated the ACCC annual meeting in Washington last week.

Moertel, Carter, Univ. of Missouri Professor John Yarbro, UCLA Jonsson Comprehensive Cancer Center Director Richard Steckel, and National Surgical Adjuvant Breast & Bowel Project Chairman Bernard Fisher discussed various aspects of the program. Excerpts from each:

Moertel: This program should make available to all cancer patients the best treatment possible. That was a mandate of the National Cancer Act a decade ago, and has not yet been achieved. Working interactions between centers and communities to transfer technology was another mandate of the Act. As for quality control, I think you can do it better. Clinical research in the community is conducted by board certified oncologists. You care for patients where they live, so you will have no problem following up your patients. With guidance on quality control, you can do it better.

It would be sheer idiocy if CCOP were to be laid on the grave of the Cooperative Group Cancer Control Program. We need both. Dr. Greenwald has assured us the cooperative group community program will be continued, and the DRCCA Board has approved it for two more years.

(Moertel objected to NCI's plan to fund research bases through the CCOPs.) All those subcontracts lying around would be a peer review nightmare. CCOPs and their research bases should be reviewed separately and funded separately.

The tithing idea—I have not the vaguest idea what it means. The whole idea should be chucked.

It would be irresponsible to fund a CCOP without a track record. There are community centers which should be funded and can demonstrate productivity. Those with potential could be funded with developmental money. The probationary method has been used responsibly by the cooperative groups for years.

I hope I have not come across as a gadfly. I'm terribly enthused by it. Dr. DeVita has fought very hard for it, against some tough opposition. We can make it work.

Carter: The concept that a well written protocol is high quality treatment. . . optimal patient care within a framework of clinical research leads to the question, is that enough? Is just participating in high quality research enough to justify this program? From my perspective, the answer is no. Ideally, this

should be integrated into broader participation with cancer control activities. We will need to meaningfully evaluate the 10 percent of those on study, and the 90 percent not. What is the impact on the 90 percent? What is the overall impact on the quality of cancer care?

I agree totally with Chuck Moertel that what we need is increased vitality. Clinical research is only as good as the ideas, and that has to come from basic science, light bulbs going on in someone's head, ideas from innovative people. Review of CCOPs must take into consideration protocols studies being performed, generation of new ideas.

I have never seen a more complex mechanism being developed. It will only work if the Cancer Institute and its staff think of all the ramifications and details and work them out ahead of time, be prepared to give us some ideas of what will be acceptable and what will not. We can never seem to get enough detailed answers to be able to plan.

We need a very clear definition of community. Who will be allowed to respond, who not. Obviously, university centers and fully funded cooperative group members should not be allowed. If a fully funded cooperative group member is allowed in, there should be a very good reason for permitting him to transfer to CCOP. There clearly is a need to bring new communities into clinical research.

There is the question of multiple affiliations with research bases. It would be possible for a CCOP to affiliate with the Southwest Oncology Group, Children's Cancer Study Group, Radiation Therapy Oncology Group, Gynecologic Oncology Group, and the NSABP. That CCOP would have to deal with five different approaches to quality control in radiotherapy, for example.

The concept of subcontracting with the research bases, including overhead, is a mind boggling procedure. That needs careful thought.

On tithing, I agree with Chuck Moertel. Fully funded members of cooperative groups do not have to put 50 patients on study, or any certain percentage. The community hospitals are being asked to do something the national groups are not. Maybe for some types of tumors, the national groups should be required to put a certain number on. Bladder, early stage ovarian, and head and neck cancer patients are desperately needed. If there is tithing, it should be across the board and apply to the national groups as well.

I don't want to be a nabob of negativism. I feel this can and will be a successful mechanism.

Yarbro: (Yarbro headed the centers program at NCI in the early 1970s, when the program was housed in the former Div. of Research Resources & Centers). Never in the history of cancer research have so many talked so long and so much about so little money. When I was in the centers program, we could spend $3 million in an afternoon ($3 million was the amount Greenwald had said several weeks ago was the total that might be required for first year CCOP funding. DeVita has always said he would make $10 million available if enough quality applications were approved).

Leo Buscher (chief of the Grants Administration Branch in DRRC and its sucessor, Div. of Extramural Activities) used to hide $3 million until the end of the fiscal year because something always came up that Palmer Saunders (then DRRC director) wanted to fund. It was interesting to watch that game, with Palmer trying to find how much Leo had hidden and Leo trying to hide just a little more than Palmer suspected he had.

Cancer control has spent $50-60 million a year for several years, and the centers program has spent vast sums. I just wish we could get on with this. A lot of people up there think you can't do it. They can't do research without residents and fellows and they think you can't either.

I think the people putting this together have had too much experience with contracts and not enough with grants. They are trying to put in too many details. I hope the RFA does have a lot of vagueness. Let the review look for quality, not details.

Steckel: A solid basis exists for collaboration between comprehensive and community cancer centers in patient care, community outreach, phase 3 and 4 studies, prevention, improving standards of patient care, profession and public education, information dissemination, psychosocial and physical rehabilitation and continuing care.

It has been assumed that research bases will come forward and actively negotiate with communities. But one cannot assume a priori that cooperation will occur. Some incentives may be lacking for centers to participate. It may not be a sufficient inducement for centers to become involved over a large range of activities. . . for a small part of $50,000. Centers can, will and do establish some relationships with communities for [joint clinical studies] with specific protocols.

If we want CCOP to succeed, further attention is needed to establish a base line standard of cancer control within a given region.

Fisher: I firmly believe in and identify with all your efforts. I am convinced that under appropriate conditions community physicians can perform high quality management of cancer patients and high quality clinical research. Their ability to do so is underdeveloped and underutilized.

CCOP could have an enormous effect on the management of cancer in the United States and the world. Right now there are a lot of micrometastatic questions—how many corner oncologists make up a CCOP, will research bases be overwhelmed with patients—I hope so. Don't become mesmerized by procedure. I'm delighted to find the keystone is clinical

trials, and the major goal is to increase the number of patients going into clinical trials.

NSABP should be considered your role model. It was the first CCOP. There is no virtue, only frustration, in being ahead of its time. We concluded that it is individuals, not institutions, who participate in clinical trials. We found that community physicians, when properly motivated and instructed in clinical trials methodology are just as good as physicians in universities in conducting clinical trials, and maybe better.

There was and is a lack of appreciation by many physicians that clinical trials are highly complicated and require strict adherence to standards and procedures. For that, I blame the medical schools.

Seventy percent of the institutions receiving NSABP funding are community hospitals or community organizations. Last year they entered 1,200 patients into studies. In our Protocol B09, two of three had at least one procedure in a community setting. Community physicians already are playing a major role, with no more delinquency than in the universities.

Community physicians can participate in clinical trials if they are willing to change their roles from recorders of history to makers of history. To do that, they have to change their mindset implanted by the medical schools.

I cannot emphasize too much the importance of considering patient numbers. In the NSABP segmental mastectomy study, 2,000 patients will not be sufficient to provide all the information we need on the various subsets.

The concept of priority rating of protocols is worthy of further pursuit. How it can be carried out escapes me.

I have to raise an eyebrow on the business of negotiating with research bases. That raises the image of smoke filled rooms, Keynesian economics, charging what the market will bear. As for the NSABP, we will do everything we can to outshoot our competition, but there is a limit.

RFPs AVAILABLE

Requests for proposal described here pertain to contracts planned for award by the National Cancer Institute unless otherwise noted. Write to the Contracting Officer or Contract Specialist for copies of the RFP, citing the RFP number. NCI listings will show the phone number of the Contracting Officer or Contract Specialist who will respond to questions. Address requests for NCI RFPs to the individual named, the Blair Building room number shown, National Cancer Institute, 8300 Colesville Rd., Silver Spring, Md. 20910. RFP announcements from other agencies reported here will include the complete mailing address at the end of each.

RFP NCI-CB-25004-46

Title: *Facility for preparing and housing virus-infected intact and chimeric mice*

Deadline: *April 29*

The Div. of Cancer Biology & Diagnosis, NCI, is seeking proposals for provision of a support facility capable of (1) maintaining a colony of up to 3,000 mice; (2) providing the technical staff and equipment capable of irradiating mice, preparing sterile cell suspensions, injecting mice intraperitoneally or intravenously with cells or virus, culturing mouse cell lines, bleeding mice, palpation of mice for detection of tumors; and (3) transporting mice and tissues twice daily between the contract facility and the Clinical Center, NIH. All animals and viruses will be supplied by the government.

The successful offeror will be required to have this facility located within 20 miles of the NIH campus in Bethesda, Md. Other minimum facility, equipment, and personnel requirements are included in the RFP.

This procurement is set aside 100 percent for small business with a size standard of "its number of employees does not exceed 500 persons." (FPR 1-1.701-1(e)(2)).

Contract Specialist: Deborah Castle
RCB, Blair Bldg. Rm 105
301-427-8877

NCI CONTRACT AWARDS

Title: Cancer Communications Network

Contractors: Univ. of Southern California, $1,326,599; Illinois Cancer Council, $670,765; Howard Univ., $707,081; Johns Hopkins Univ., $601,947; New York State Dept. of Health, $595,349; Mayo Foundation, $623,964; and Univ. of Miami, $773,248.

Title: Phase 1 studies of new anticancer agents, continuation

Contractor: Mt. Sinai School of Medicine, New York, $31,208.

Title: Phase 1 and 2 studies of new anticancer agents, continuation

Contractors: Mayo Foundation, $62,084, and Memorial Hospital for Cancer & Allied Diseases, $42,873.

Title: Transplantation, induction and preservation of plasma cell tumors in mice and the maintenance of special mouse strains

Contractor: Litton Bionetics, $3,555,746.

The Cancer Letter _Editor Jerry D. Boyd

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